REMARKS

I. INTRODUCTION

The foregoing listing of claims is intended to set forth the claim set as previously presented by the Applicants in a paper filed July 13, 2004. No further amendments are intended.

II. TRAVERSAL OF RESTRICTION

For reasons set forth below, the restriction is improper and should be withdrawn.

A. No substantial burden on PTO; fairness to applicants

The extensive prosecution history of this application demonstrates that examination of the entire current claim set is not a serious burden on the PTO. Accordingly, the restriction is improper, and should be withdrawn. See MPEP 803 ("If the search and examination of an entire application can be made without serious burden, the examiner **must** examine it on the merits, even though it includes claims to independent or distinct inventions.") (Emphasis added.)

The previous examiner already has demonstrated that search and examination of the entire application, with claims directed to polypeptides and fibers/polymers, can be made without serious burden. The application as originally filed included 100 claims, although a number of claims were canceled to reduce excess claim surcharges.

On October 2, 2001, the first examiner issued a first restriction requirement, alleging four distinct inventions. Group I was stated to be "drawn to polynucleotides and chimeric polypeptides" with the other three groups directed to various methods.

In response to a traversal by the Applicants, the first examiner issued a second restriction requirement on April 9, 2002, identifying six restriction groups, two "polynucleotide" groups, two "polypeptide" groups, and two "method" groups. (See Paper No. 13.) Notably, Group V (elected by the applicants with traverse), included

claims drawn to **both polypeptides having a reactive SCHAG amino acid sequence and fibers/polymers (see, e.g., claim 67).** The restriction also included a somewhat vague *election of species*, in response to which the Applicants elected a peptide comprising SEQ ID NO: 2, with a cysteine substitution, with a metal atom substituent, with traverse.

Following the second restriction and election, the prosecution included at least three substantive office actions on the merits (dated 10/30/02; 4/22/03; and 1/13/04) with substantive amendments/responses filed in response to each. Throughout this substantive prosecution, the applicants pursued claims to both polypeptides and claims to fibers/polymers, and the examiner searched and examined such claims. This approach to prosecution was perfectly reasonable because the fibers/polymers are comprised of polypeptides.

This prosecution history conclusively establishes that examination of all of the current claims -- including claims drawn to both polypeptides and fibers/polymers comprised of the polypeptides -- can be examined without serious burden. The fact that a first examiner has performed searching and extensive examination should lessen the burden on the new examiner.

B. No burden with respect to SEQ ID NO:2 and substitutions

To the extent that the Applicants are restricted to pursuing claims limited to a yeast prion sequence or more specifically, to claims related to SEQ ID NO:2, there will be no serious burden to examining claims that embrace substitutions at more than one elected residue. The first Examiner, who already examined generic claims, relied on a substituted amyloid beta prior art document as the motivation to substitute, and this reference has been distinguished by the Applicants. Moreover, the first Examiner deemed claims 117 and 118 allowable, and claims 117 and 118 encompass two different substitutions in SEQ ID NO:2 - amino acid position 184 in claim 117 and amino acid position 2 in claim 118.

C. Failure to identify characteristics that define the restriction groups

Each of the eleven restriction groups is directed to a polypeptide, a fiber comprised of polypeptides, or a polymer comprised of polypeptides. The Patent Office has wholly failed to explain what characteristics distinguish one polypeptide group from another; or one fiber group from another; or one polymer group from another; or a fiber group from a polymer group. Moreover, Group VI, a "polypeptide" group, includes at least one "fibrous polymer" claim, indicating that polypeptides and fibrous polymers are not believed to be restricted per se from each other.

This abbreviated method of issuing a restriction requirement ignores the MPEP-directed practice of "identifying each separate subject amongst which restriction is required, and grouping each claim with its subject." (MPEP 814.) Instead, the Patent Office has seemingly grouped claims (originally examined together) into eleven groups based on independent claims, and left it to the applicants to guess at what "subjects" define the eleven distinct groups. "A mere statement of conclusion is inadequate." MPEP 816. Each relationship of claimed invention should be treated and the reasons for concluding distinctness should be set forth, according to the MPEP. If the restriction is maintained, the applicants request that the reasons be further articulated to give a fair opportunity to respond.

D. The restriction of fiber/polymer claims into eight separate restriction groups I-V and IX-XI was improper.

Notwithstanding a few boilerplate statements about "divergent structure" and "different effects" that might be alleged by any examiner in any generic restriction requirement, the Patent Office has failed to articulate any basis for restricting claims directed to fibers/polymers into eight distinct groups (or nine groups

if Group VI is included).[1] These generalized statements are contradicted by the later admission that "All claims are in part directed to a 'SCHAG amino acid sequence' as generically claimed." Thus, the Patent Office recognizes that there is a commonality between all of the groups - not a divergence.

In fact, a fiber/polymer comprised of the originally elected species, a yeast SEQ ID NO: 2 prion with a cysteine substitution with a metal atom substituent, falls within virtually every one of the allegedly distinct groups.[2] A restriction requirement in which one species falls within every restriction group is improper on its face, because a species cannot be independent or distinct from itself.

E. The restriction of polypeptide claims into three separate restriction groups VI-VIII was improper.

The arguments in Part B are applicable to the three alleged polypeptide restriction groups as well. A polypeptide comprising SEQ ID NO: 2 SCHAG sequence with a cysteine substitution (generically, as originally elected) falls within all three groups. A polypeptide comprising SEQ ID NO: 2 with a cysteine modifications at position 184 would fall within Groups VI and VIII. A polypeptide comprising SEQ ID NO: 2 with a cysteine modification at positions 2 and 184 would fall within Groups VII and VIII. As noted above, Group VI includes a claim directed to a polymer, and therefore would overlap with multiple members of the eight "polymer/fiber" groups. A restriction group cannot define an independent and distinct group when it overlaps with another group.

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[1] The restriction requirement also contains some statements about Alzheimer's and Scrapie diseases, but these statements are not particularly relevant to the invention because the focus of this invention relates to polypeptides and fibers/polymers with properties useful for industrial applications and nanotechnology. None of the claims are directed to methods of treating pathologies. Likewise, there are statements about use in detection or generation of antibodies for labeling, but those statements are tangential to the claimed invention.

[2] Group III requires two reactive side chains and would not read on a species having only one such side chain. But, several claims in other groups specify "at least one" reactive side chain and, therefore, overlap in scope with Group III.

F. The requirement to "delineate the molecular embodiments to which the claims will be restricted" is improper.

The MPEP identifies certain circumstances in which an examiner may require an applicant to *elect a species* of invention, to which the claims may be restricted *if no generic claim is allowed.* However, the Examiner has specifically required an election of a "molecular embodiment" and asserted that such election is NOT a species election, and indicated an intention to refuse to examine generic claims. ("The subject matter for examination will be restricted to the extent of the subject matter elected.") The Applicants request that the authority for such a restriction be identified or the "molecular embodiment" restriction be withdrawn.

The molecular embodiment restriction effectively turns what on its face is an eleven-way restriction, into a restriction of hundreds or thousands or millions of groups. The eleven-way restriction has been overlaid atop a six-way restriction of the original claims, creating an estimated 11x6=66 groups if the entirety of the original claim set is considered. The examiner requires electing between at least thirteen sequences in the sequence listing, expanding the restriction to "at least" 66x13=858 groups. However, the restriction does not end there because "the specific SCHAG sequence is required to be delineated along with the specific amino acids of the sequence and where in generic form any substitution should be deemed to occur." To pick one example, the Applicants demonstrate in the application that numerous fragments of SEQ ID NO: 2 are effective to practice the invention and demonstrate that multiple residues of SEQ ID NO: 2 can be an effective point of substitution of a reactive side-chain amino acid such as cysteine. If each fragment and each substitution of each fragment are deemed "molecular embodiments" to which the claims would be restricted, then the number of restriction groups grows exponentially into the thousands or millions. Neither the present applicant (an academic institution) nor any other applicant could afford to protect the full scope of the invention that has been disclosed to the public through the patent application, and the Patent Office could not hire enough examiners to examine the thousands or millions of divisional applications that would be required! The first examiner had no apparent difficulty examining the present application as originally filed based on a six-way restriction, and no valid basis exists for expanding it to thousands or millions of groups. Generic

claims are permitted in every other technology and there is no rule or statute prohibiting generic biotechnology inventions[3].

III. ELECTION

A. Election of Group

Applicants hereby elect Group VII (claims 121-123, 139 and 144), drawn to polypeptides having a SCHAG amino acid sequence.

B. "Delineation of molecular embodiment"

With respect to election of a molecular embodiment, Applicants hereby elect *S. cerevisiae* Sup35 polynucleotides and polypeptides (SEQ ID NO:2), and more particularly the NM regions (residues 1-253) and still more particularly the N region (amino acids 1-123) of this sequence. If election of a single modification is required, the Applicants hereby elect substitution of a cysteine residue into the Sup35 sequence. If election of a single location is required, Applicants elect a cysteine substitution at amino acid position 2.

IV. REQUEST FOR REJOINDER

Even if the restriction is maintained, the applicants request the opportunity to present (and have rejoined) fiber/polymer claims that depend from and are limited by polypeptide claims that may be deemed allowable.

V. FINALITY

The restriction requirement is stated to be a "final" action, a notification believed to be a typographical error. If final, then the applicants request clarification of what claims stand rejected, and request that this submission be treated (additionally) as a Notice of Appeal, with any necessary appeal fee charged to Deposit Account No. 13-2855.

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[3] In fact, the recent TC1600 Restriction Training for Examiners (August 2004) has numerous examples of structurally divergent molecules and other genera examined together in a single restriction group. (See, e.g., 1610/1620 Example 1 (emollients and humectants examined as a genus despite divergent structures) and Example 2 (chemical genus); and 1630/1640/1650 Example 1 (DNA and polypeptide genera)

VI. CONCLUSION

For the foregoing reasons, the applicants request that the restriction be withdrawn and prosecution continued on the merits.

Respectfully submitted,

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